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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,174	10/29/2003	Swaminathan Jayaraman	795-A03-004	7393
33771	7590	03/17/2005	EXAMINER	
PAUL D. BIANCO: FLEIT, KAIN, GIBBONS, GUTMAN, BONGINI, & BIANCO P.L. 601 BRICKELL KEY DRIVE, SUITE 404 MIAMI, FL 33131				GHERBI, SUZETTE JAIME J
ART UNIT		PAPER NUMBER		
3738				

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/696,174	JAYARAMAN, SWAMINATHAN	
	Examiner	Art Unit	
	Suzette J Gherbi	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 January 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,5-14 and 16-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,5-14 and 16-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/11/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment and comments dated 1/4/05 have been received in application serial number 10/696,174. Claims 3-4, 15 have been canceled.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-2, 5-13, 16-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the specification for the term "existing" as claimed in 1, 17 and 23, there is only support for the phrase "disease process of the vascular disease."

4. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. There is no support in the specification for the primer layer includes one of a bioabsorbable polymer and a biostable polymer. The specification in section [0052] states that:

The intravascular implant may include a primer layer upon which the coating is applied. The primer layer may be made of a bioabsorbable polymer or a biostable polymer. Also, the coating may include a top coat applied over the coating.

The specification gives an *either or* example but not both types of polymers together as currently claimed in 14.

5. Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the specification for the phrase "wherein coating the intravascular implant is performed at the procedure site". Applicant states in the remarks that support for this new limitation is found in [0094] however section [0094] only discloses that "...an implant may be coated with at least one therapeutic agent or a pre-coated implant having the desired therapeutic agent or agents may be obtained." This is totally different from the claimed subject matter because as taken in context of the specification the implant can be coated in another department other away from the procedure cite (even if it's in a room adjacent the procedure site per say).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 5, 6-11, 17, 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Falotico et al. 2003/0060877. Falotico et al. discloses the invention as claimed comprising: Identifying a disease process in the pathology of vascular disease (see [003-0012]); selecting a first agent to treat or prevent the disease; coating a portion of the intravascular implant with an effective amount of the first agent; then utilizing a second agent to treat or prevent the vascular disease by applying it to the implant (see [0032]); identifying using an MRI or other devices [0026]; wherein an agent is a calcium [0012]; wherein a polymer matrix (biodegradable) is utilized [0201].

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 2, 12-14, 16, 18-22, 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falotico et al. 2003/0060877. Falotico et al. has been disclosed above however Falotico et al. does not specify that (a) the disease process is identified using genetic determination or (b) coating the intravascular implant at the procedure site. It would have been obvious to one having ordinary skill in the art at the time the invention was made to examine a patients background information to determiner whether they were "genetically" pre-disposed for vascular disease and is a well known procedure performed during medical evaluation; It is also obvious that a surgeon would first "identify" (which equates to identifying he disease process) where the disease is located (i.e. via imaging) before advancing an implant such as a stent in order to know the correct placement of the device.

Response to Arguments

10. Applicant's arguments filed 1/4/05 have been fully considered but they are not persuasive. Applicant has amended the claims, yet as noted above for some of the amendments there is a lack of supporting the specification. Nevertheless, the Falotico et al. patent discloses the invention as currently claimed. Applicant contends that Falotico does not teach the identification of a specific disease process and that he simply list various disease processes. It is noted that applicant does not claim a

"specific" disease process, regardless applicants invention also discloses various disease processes (see [0085} which are the same as some of the diseases listed by Falotico et al. Applicant has further amended the claims to state that the disease process is identified using genetic determination. While this limitation is disclosed in the specification in section [0086], no definition or criticality is associated with the term "genetic determination" therefore as best understood it is obvious the heart disease can be genetically linked as is well documented and this is an obvious identifying factor when diagnosing a patient.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

12. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

13. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Suzette J-J Gherbi
10 March 2005